

# Notice of Allowability

## Application No.

09/983,025

## Examiner

Delia M. Ramirez

## Applicant(s)

OXVIG ET AL.

## Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/13/2006.
2. ☒ The allowed claim(s) is/are 12,18,19,49-52,55-58,75,83,87,90-93,95-101,105,108 and 110-117.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 12, 18-19, 49-52, 55-58, 75, 83, 87, 90-93, 95-101, 105, 108, 110-117 are pending.

Amendment of claims 12, 83, 105, addition of claims 112-117, and amendments to the specification in a communication filed on 1/13/2006 are acknowledged.

In a telephone conversation with Mr. Iver Cooper on 2/9/2006, an agreement was reached to amend claims 105, 112 and 113 to place the application in condition for allowance.

### ***Examiner's Amendment***

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this Examiner's amendment was given in a telephone interview with Mr. Iver Cooper on 2/9/2006.
3. Please replace claims 105, 112-113 as follows:

105. The polypeptide of claim 12 wherein said additions, if any, are of 1 to 5 amino acid residues, and said deletions, if any, are of 2 to 5 amino acid residues.

112. A method for producing the polypeptide according to claim 18, said method comprising the steps of

- (i) providing a transfected or transformed host cell comprising a recombinant DNA molecule in the form of an expression vector, said vector comprising an expression signal operably linked to a polynucleotide sequence encoding said polypeptide;

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- (ii) culturing the transformed host cell under conditions suitable for expression of said polypeptide, and
- (iii) recovering the polypeptide so expressed.

113. The method of claim 112 wherein the host cell is a mammalian cell.

### ***Reasons for Allowance***

4. The following is an Examiner's statement of reasons for allowance. Although the prior art discloses a human PAPP protein (see teachings of Farr et al. discussed in previous Office Actions), the Examiner has found no teaching or suggestion in the prior art directed to a polypeptide which comprises SEQ ID NO: 2, consists of amino acid residues 234-1791, or is 95% sequence identical to amino acids 234-1791 and differs from amino acid residues 234-1791 solely by (i) conservative substitutions, or (ii) additions or deletions of up to 10 amino acids from the N or C terminus. Therefore, claims 12, 18-19, 49-52, 55-58, 75, 83, 87, 90-93, 95-101, 105, 108, 110-117, directed to a polypeptide comprising SEQ ID NO: 2, consisting of amino acid residues 234-1791 of SEQ ID NO: 2, comprising amino acid residues 1-22 and 234-1791 of SEQ ID NO: 2, 95% sequence identical homologs having proteolytic activity against IGFBP-5, specific fragments of SEQ ID NO: 2, a method to recombinantly produce the polypeptide, and a method to detect inhibitors and enhancers of the proteolytic activity of the polypeptide, are allowable over the prior art of record.

### ***Conclusion***

5. Claims 12, 18-19, 49-52, 55-58, 75, 83, 87, 90-93, 95-101, 105, 108, 110-117 are allowed.

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6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
February 10, 2006

  
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